

**IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
WESTERN DIVISION (TOLEDO)**

**PLAINTIFF'S MEMORANDUM IN SUPPORT
OF MOTION FOR NEW TRIAL**

Under Federal Rule of Civil Procedure 59, Plaintiff Tina Burris respectfully would show the Court that Ethicon invited prejudicial error in the admission of Exhibit 1156, the “Surgeon’s Monograph,” by laying a foundation for the document through the testimony of its retained expert Dr. Larry Sirls, who *recanted* his foundational testimony after the Court had admitted the document and allowed extensive testimony about it. During the nine-year pre-trial proceedings for this case in MDL No. 2327, Ethicon failed to include the Monograph in its discovery responses identifying the warnings information it provided to physicians for the Prolift device. The Monograph and related testimony provided highly probative and misleading evidence on the question that the jury decided in Ethicon’s favor, resulting in the verdict for Ethicon. Plaintiff accordingly asks the Court to order a new trial in the interests of substantial justice.

FACTS

Plaintiff Tina Burris direct-filed this product liability action against Ethicon in MDL No. 2327 eight years ago, seeking recovery for personal injuries caused by the implantation of

Ethicon's Prolift mesh sling device.¹ (Doc. 1). Coordinated pretrial proceedings—Involving thousands of plaintiffs—occurred over a nine-year period in MDL No. 2327, consisting of general fact discovery (including the production of millions of Ethicon documents and depositions of more than 115 corporate representatives and other general fact witnesses), general expert discovery on eighty retained defense experts including those designated in this case, general dispositive motion and *Daubert* practice, and bellwether trials on several Ethicon products including the Prolift device at issue here. On July 21, 2020, the MDL court transferred three dozen Ethicon cases (including this one) for trial in their originating jurisdictions, urging the receiving courts to “immediately set these cases for trial.” (Doc. 55) at 1-2. After resolving case-specific pre-trial motions, this Court conducted a jury trial last month on Ms. Burris’s claim under Ohio law for strict liability failure to warn.

At trial, one hotly-disputed issue concerned possible warning information Ethicon had conveyed to Ms. Jarrett’s surgeon, Dr. Desnere Brown, beyond what Ethicon disclosed in its “Information for Use” for the Prolift device. Ethicon focused heavily on key information about the frequency and severity of Prolift’s risks to patients, found only in Defense Exhibit 1156, a “Surgeon’s Monograph” that Ethicon’s retained general expert, Dr. Larry Sirls, testified he had given to Ethicon in 2012. Tr. 1129:5-13, 1137:15-18, 1139:19-20, 1140:1-12. During pretrial discovery in MDL 2327, as best as Plaintiff’s counsel can determine,² Ethicon did not identify the

¹ Ms. Burris also asserted claims arising from the implantation of Ethicon’s TVT-Secur device, but those are not at issue in this motion.

² Plaintiffs’ counsel thoroughly investigated this issue based on available records from MDL 2327, but did not serve on the Plaintiffs’ Steering Committee or otherwise manage or conduct pre-trial proceedings on behalf of the MDL plaintiffs, and thus face significant hurdles locating such information within the voluminous discovery records from the 9-year-long MDL proceeding..

Surgeon's Monograph in response to the interrogatory aimed at discovering what warnings information Ethicon provided to physicians. *See Exhibit A* (Defendants' Third Supp'l Resp. to Pls' First Set of Interrog., dated Aug. 9, 2013) at 3-7 (identifying what "warnings, information or notifications, if any, [Ethicon] provide[d] to health care providers and patients concerning the use and Complications of Pelvic Mesh Products."). Dr. Brown, who had attended an Ethicon Prolift cadaver lab training in April 2008, could not recall ever having received or seen the Monograph, and she was unfamiliar with the information it contained. Tr. 862:15-17, 864:2--865:12, 858:8-15, 916:22-917:19.

Over Plaintiff's objections, the Court first allowed Ethicon to publish the Monograph, and then admitted it into evidence, based on testimony by Ethicon's retained expert, Dr. Larry Sirls. *See* Tr. 855:3-6, 864:17-18, 1137:15-18, 1140:1-12. Dr. Sirls testified, in particular, that Ethicon had provided him with the Monograph at the first Prolift cadaver lab training he attended in 2005. *See* Tr. 1129:5-13, 1137:15-18, 1139:19-20, 1140:1-12. Dr. Sirls subsequently recanted that testimony. Tr. 1204:7-20, 1217:24-1218:5. Nevertheless, the Monograph remained in evidence and Ethicon's witnesses and counsel placed heavy emphasis on the warnings Ethicon had supposedly conveyed to Dr. Brown in the Monograph.

The jury ultimately found *for* Ethicon on the issue of whether "the Prolift product was defective in its warnings at the time it was manufactured," and thus entered a verdict in favor of Ethicon. (Doc. 250). The Court entered a final judgment in favor of Ethicon on July 21, 2022. (Doc. 252). This motion under Federal Rule of Civil Procedure 59 is filed on the 28th day after entry of the judgment.

LEGAL STANDARD

Under Rule 59 of the Federal Rules of Civil Procedure, the court may grant a new trial on all or some of the issues “for any reason for which a new trial has heretofore been granted in an action at law in federal court.” Errors in the admission or exclusion of evidence are grounds for a new trial when they affect a substantial right of a party. *See Fed. R. Civ. P. 61; Logan v. Dayton Hudson Corp.*, 865 F.2d 789, 790 (6th Cir. 1989) (affirming order granting new trial where one party’s expert testified beyond the scope of his qualified expertise to the substantial harm of the opposing party).

ARGUMENT

The admission of Defense Exhibit 1156, a 41-page monograph purportedly containing additional warnings information given to surgeons about Ethicon’s Prolift device, resulted in prejudice that warrants a new trial in the interest of substantial justice. Fed. R. Civ. P. 61. Ethicon could not authenticate or lay a foundation for the exhibit through the testimony of Plaintiff’s treating physician: Dr. Brown herself did not recall precisely what written materials were provided by Ethicon at the training course she attended for Ethicon’s Prolift device. Tr. 862:15-17, 864:2-10. She did not recognize Exhibit 1156 (“the Monograph”) and consistently testified that she did not recall ever having received it:

A. I don't remember this specific thing. Like I said, if you have a sheet that says I got it, maybe. I don't remember.

Q. I'm sorry. I wear a hearing aide and I didn't hear you.

A. I said I don't remember this specific paper. If you have some kind of a sign-in sheet that says I got it, then, of course, I got it. But this specific thing, I don't.

...

A. I don't remember getting this, no.

Tr. 865:4-15; *see* Tr. 864:15-865:12, 868:8-15 (“I don’t remember ever seeing this paper.”), Tr. 916:22-917:19 (“I don’t recall seeing it.”). Dr. Brown acknowledged at most that it was “possible” she received the Monograph at the training “if they say they gave it or if I signed for it or something,” since, as she repeatedly testified, she received the same materials given to other surgeons at the training. Tr. 865:19-20; *see, e.g.* Tr. 864:9-10 (“If it was given to everybody, I got it, yes.”). Yet Ethicon at no point in the trial attempted to offer documentary evidence of such sign-in sheets or other record showing it had distributed the Monograph to surgeons at the Prolift cadaver lab Dr. Brown attended.

Plaintiff objected to the publication of Exhibit 1156 in conjunction with Dr. Brown’s testimony on the basis of hearsay and lack of foundation. Tr. 866:3-6; 864:17-18. The Court overruled this objection and Ethicon published the document during the testimony of Dr. Brown, at which point Ethicon began referring to it as material that “Ethicon made available to doctors who attended its training.” *See, e.g.*, Tr. 868:8-15. Defense counsel then represented to Dr. Brown—who had testified that it was “possible” she received the Monograph at the training “if they say they gave it or if I signed for it or something,” Tr. 865:19-20—that Ethicon would present evidence that the document “was made available to doctors like you who attended the cadaver professional education training in August [sic] 2008,” and began pointing out information in the document that appeared to contradict Dr. Brown’s earlier testimony that Ethicon had not given her relevant warnings about the risks of the Prolift mesh. *See, e.g.*, Tr. 868:22-869:8, 878:16-880:10.

Ethicon eventually persuaded the Court to admit the Monograph—over Plaintiff’s objection—through the testimony of Ethicon’s retained expert, Larry Sirls, M.D. Dr. Sirls initially testified he had received the Monograph when he first attended an Ethicon-sponsored Prolift cadaver lab training in 2005, and that he had given the document to Ethicon’s counsel in 2012.

Tr. 1129:5-13, 1139:19-20. The Court apparently found Dr. Sirls' testimony persuasive in deciding to overrule Plaintiff's repeated objections that the document was hearsay lacking a sufficient foundation:

MS. KNUTSON: Your Honor, at this time, defense moves for admission of Exhibit 1156 into evidence.

MS. BOSSIER: Objection, Your Honor. It's hearsay.

MS. KNUTSON: It came from our files, Your Honor. I think we've established that makes it not hearsay.

THE COURT: You got it as part of your training initially -- it's not training to be a trainer but when you were training to be a surgeon performing the Prolift procedure?

THE WITNESS: Yes, sir.

THE COURT: I'm going to overrule the objection.

Tr. 1140:1-12; *see also* Tr. 1137:15-18.

After the Court had admitted Exhibit 1156, when confronted with evidence that the Monograph had not been written or published in 2005 when he attended the Prolift cadaver lab training, Dr. Sirls admitted that his "dates were wrong" and he in fact had *not* received the Monograph or the data it contained during his training from Ethicon. Tr. 1204:7-20; 1217:24-1218:5; Exhibit 523 (2007 email forwarding draft monograph). Indeed, Dr. Sirls admitted that he had no idea when the Monograph became available to other surgeons, or whether that occurred before or after Ms. Burris's implant. Tr. 1206:8-14. Thus, no witness could authenticate Exhibit 1156 as part of Ethicon's written materials that were distributed at the Prolift cadaver lab training

that Dr. Brown attended in 2008 or confirm that the Monograph fell within any exception to the rule against the admissibility of hearsay. Fed. R. Evid. 801(c), 901.

Ethicon's failure to disclose Exhibit 1156 among its Prolift warnings materials during general discovery in MDL 2327, in and of itself, justifies the grant of a new trial in which Ethicon's use of the Monograph is precluded entirely, as a sanction under Federal Rule of Civil Procedure 37 and/or to rectify the fundamental unfairness created by Ethicon's use of the Monograph in Ms. Burris's trial. Ethicon failed to identify the "Surgeon's Monograph" and/or Exhibit 1156 as part of the warnings or information it conveyed to physicians. *See* Ex. A (Defendants' Third Supp'l Resp. to Pls' First Set of Interrog.) at 3-7. Understandably, this left Plaintiffs' counsel in this remanded case surprised and unfairly prejudiced when Ethicon arrived at Plaintiff's trial claiming it had provided Dr. Brown with the Monograph with additional warnings of the risks associated with the Prolift device via the information contained in the Monograph. Nor did Plaintiff's counsel have any reason to know that Dr. Sirls would testify that Dr. Brown had received the Monograph at a cadaver lab training: as Plaintiffs' counsel pointed out during the trial, Dr. Sirls' Prolift General Report discussed his experience with Prolift trainings and the adequacy of Ethicon's warnings, but never cited or mentioned Ethicon's distribution of the Monograph as a basis for his opinions. *See* Exhibit B (General Expert Report of Larry T. Sirls, M.D., dated February 11, 2017) at 52-54. Dr. Sirls even prepared an addendum to his Prolift report in 2019 but again made no reference to the Monograph. *See* Exhibit C (Addendum to Expert Report of Larry T. Sirls, dated March 21, 2019). For Ethicon to suddenly make the Monograph a capstone of Dr. Sirls' opinion testimony suggests a lack of diligence in disclosing "a complete statement of all opinions the witness will express and the basis and reasons for them" as required by Federal Rule of Civil Procedure 26(2)(B)(1).

The error Ethicon itself invited by publishing and offering into evidence the Monograph without a sufficient foundation rises to the level of harmful error that justifies a new trial, because the Monograph and related testimony is highly likely to have impacted the jury's verdict. As the Court itself observed during the trial, Ethicon elicited testimony from Dr. Brown using the Monograph that casts doubt upon her direct testimony that Ethicon had not provided her with certain key warnings about the use of Prolift mesh. *See, e.g.*, Tr. at 1051:19-24 (describing the Court's "dilemma with the warning" arising from Dr. Brown's testimony). Ethicon then questioned its retained expert, Dr. Sirls, at length about the warnings supposedly conveyed at its professional trainings using the Monograph. *See, e.g.*, Tr. 1134:20-1135:6, Tr. 1140:17-1145:17. Ethicon likewise emphasized the Monograph in questioning its expert, Dr. Khandwala, who gave testimony suggesting that *he* used the Monograph in Prolift trainings *he* gave, but who had no personal knowledge of what happened at other trainings such as the one Dr. Brown attended. Tr. 1460:16-1461:2; 1472:14-1478:23; 1505:8-1507:17; *see also* Exhibit D (Defense Fact Sheet & training records) at DFS-BURRIS.TINA-0002 & 0093 (failing to identify Dr. Khandwala as a person affiliated with Ethicon who had contact with Dr. Brown or conducted her training in Dayton, Ohio in April 2008). Ethicon's counsel emphasized the information Ethicon purportedly conveyed in the Monograph during closing arguments. Tr. at 1703:10-1704:19. The jury's fifth and final question to the Court immediately prior to returning a verdict in Ethicon's favor concerned the timing of when the Monograph was published. Tr. at 1792:9- 1794:21. In short, the Monograph was highly probative evidence on the question that the jury determined in Ethicon's favor (whether there was a defect in Ethicon's warnings), and its improper use and admission, based on foundational testimony that the witness later recanted and particularly given the Court's decision to limit what evidence Plaintiffs could use to put the Monograph into context, justifies a new trial.

CONCLUSION

The admission of the Surgeon's Monograph (Exhibit 1156) based on a foundation that Ethicon's expert later recanted resulted in prejudicial error that requires a new trial in the interest of substantial justice. Plaintiff Tina Burris prays that the Court grant her motion for new trial pursuant to Rule 59 and order a new trial on all issues.

Dated: August 18, 2022

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on this 18th day of August, 2022, I electronically transmitted the attached document to the Clerk's Office using the CM/ECF System for filing and transmittal of a Notice of Electronic Filing.

/s/ Rachel L. Wright

Rachel L. Wright